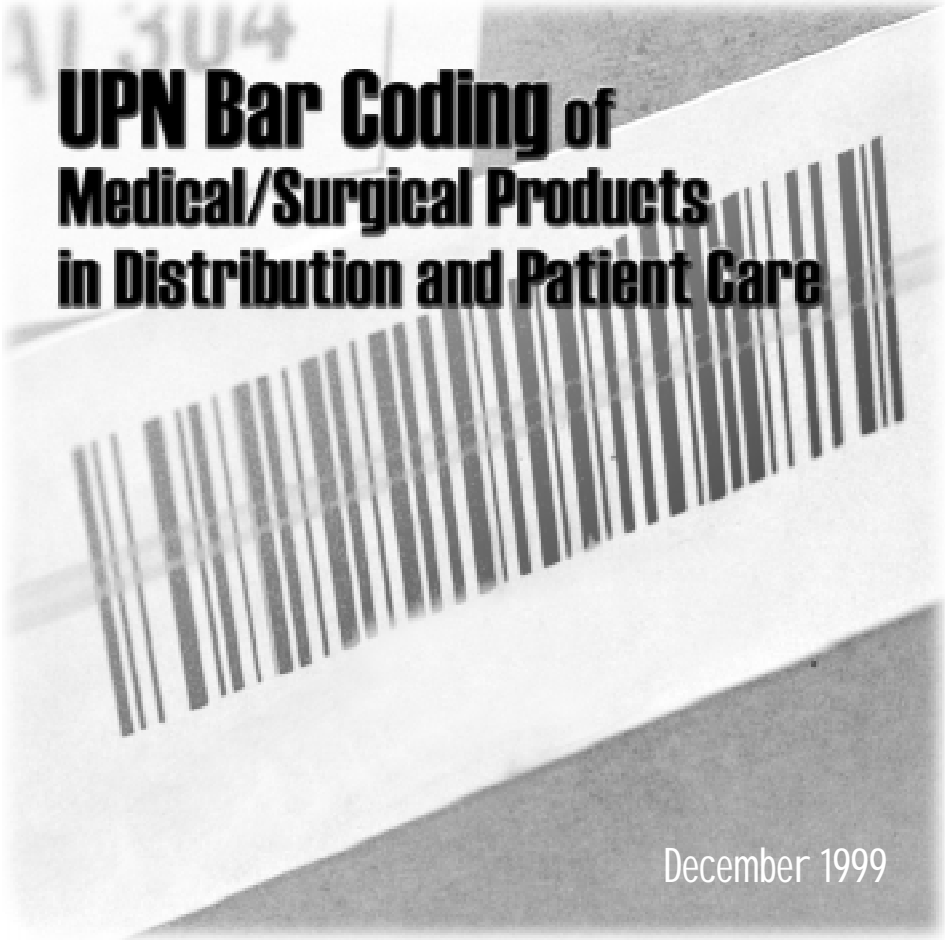




Health Industry Distributors Association

The background of the cover features a grayscale photograph of a medical product, possibly a box or bag, with a large barcode and the number '41304' printed on it.

UPN Bar Coding of Medical/Surgical Products in Distribution and Patient Care

December 1999

Barcode Position Paper

Contents

HIDA.....	1
The Health Industry Bar Code Supplier Labeling Standard.....	1
Benefits and Applications.....	1
Bar coding applications.....	2
Electronic Data Collection (EDC) opportunities.....	2
Electronic Data Interchange (EDI) system applications.....	2
Inventory management applications.....	2
Medical/surgical manufacturer/labeler benefits.....	2
Medical/surgical distributor benefits.....	2
Medical/surgical health care facilities benefits.....	2
Safe Medical Devices tracking.....	3
U.S. Department of Defense.....	3
Universal Product Numbers (UPN).....	3
HIDA Position.....	4
HIDA Bar Code Format Recommendation.....	5
Manufacturers with product catalog numbers greater than 13 positions.....	6
Secondary data structures.....	6
Identifying Shipping Containers.....	6
Examples.....	7
Bar Code Label.....	7
Bar Coding Location Example for Shipping Case Packaging.....	8
Bar Coding Location Examples for Boxes (Shelf Pack).....	8
Packaging Indicators for Standard and Alternate Packaging Hierarchies.....	9
For Further Information.....	10

HIDA

The Health Industry Distributors Association is the national business trade association representing more than 600 medical product distributors and home healthcare companies. HIDA's wholesale and retail members serve the Home Care, Hospital, Long Term Care, Physician/Alternate Care, and Imaging markets. The HIDA Educational Foundation (HEF) is the non-profit research and education organization affiliated with HIDA.

HIDA is devoted exclusively to providing outstanding and timely services which anticipate and meet the unique and ever-changing needs of its members. HIDA's services include industry information and data, educational products and programs, and representation on regulatory and legislative issues.

The Health Industry Bar Code Supplier Labeling Standard

The Health Industry Business Communications Council (HIBCC) is the standards-setting body for the healthcare products industry. HIBCC's members are the following national organizations:

The American Hospital Association
The American Medical Association
The American Society for Automation & Pharmacy
The American Veterinary Distributors Association
The Healthcare Information & Management Systems Society
The Health Industry Distributors Association

Health Industry Group Purchasing Association
The Health Industry Manufacturers Association
The National Wholesale Druggists' Association
The Pharmaceutical Manufacturers Association
The U. S. Department of Defense

In March 1984, HIBCC (then the Health Industry Bar Code Council) adopted and published a document titled *the Health Industry Bar Code (HIBC) Supplier Labeling Standard*. This document was modified in 1994 to be consistent with UCC/EAN specifications. It describes the format (data structure) intended for use between a supplier or packager of healthcare products and the recipient, provider, handler or user of those products. It also describes the bar code symbol presentation of that format. The *HIBC Bar Code Supplier Labeling Standard*, along with the *HIBC Provider Applications Standard*, issued subsequently, make up the *HIBC Standards*.

Automatic identification technology is continually evolving. As technological advances prove applicable to the healthcare industry, HIBCC incorporates them into a revision of the standard, wherever possible. Every attempt is made to maintain existing data structures, thereby allowing new technologies to be introduced into systems in a non-disruptive manner.

It is intended in the Standard that healthcare products be labeled with a Primary Symbol, and, if necessary, with a Secondary Symbol. Distinction must be made between the terms "data structure" (often called code) and "symbolology." Code refers to the actual data to be encoded, whereas symbolology refers to the machine-readable technique used to encode the data.

The purpose of the Primary Symbol is to identify the labeler, the product code, and the unit of measure. The Standard allows for two labeling options. The UCC/EAN and HIBC LIC structures encode similar data in different formats.

Benefits and Applications

With continuing pressure on healthcare costs and healthcare products distributor margins, and enhanced low-cost technical capabilities and efficiencies, the need is even greater to identify ways and means to take advantage of technology to benefit distribution and patient care in this country. Automatic identification technology represents an important opportunity that deserves attention today. While bar coding is not new, it is not yet widely used in healthcare and can provide many benefits.

Bar coding applications

Additional medical/surgical distribution and patient care efficiencies can be achieved by the use of bar codes on all medical/surgical products. Shipping cases, inner packs (or intermediate packaging), units of use ("eaches"), and pallets, when bar coded, can be handled more efficiently and accurately via scanning.

Electronic Data Collection (EDC) opportunities

Bar coded products are a major enabling factor to automate input and collection of transaction data. Eliminating handwritten documents and subsequent manual keystroke entries can result in significant productivity gains and a near 100 percent accuracy level. These can accrue to both operations and administration functions of all trading partners and healthcare providers. Thus, Electronic Data Collection (EDC) of recurring bar coded data adds value to Electronic Data Interchange (EDI).

Electronic Data Interchange (EDI) system applications

Bar coded products allow data input speed and accuracy advantages to accrue to EDI systems. Input of information from healthcare facilities, distribution points, and manufacturers can be expedited by bar code interface system to network computers. EDI and bar coding tie the product to the information quickly and accurately.

Inventory management applications

Bar coded products provide efficiencies in inventory control and cost accounting for healthcare providers. Bar coded, shelf-location labels reserve space for items selected for stocking. Replenishment and inventory counts of distribution levels can be easily, promptly, and accurately input by bar codes available on products and shelf locations. Many providers currently have products labeled with bar codes by their distributors. Once products are source-coded this costly relabeling will be eliminated. Medical/surgical manufacturers, distributors, and providers all gain.

Medical/surgical manufacturer/labeler benefits

Medical/surgical manufacturers can gain major efficiencies through the use of bar coding. Production, quality control, warehouse location recording, order sorting, shipping, and returns processing can all profit from the use of bar codes on shipping cases, inner packs (intermediate packaging), and units of inventory (eaches). Manufacturers benefit by getting products to customer locations and information into their computer systems faster and more accurately.

Medical/surgical distributor benefits

By utilizing integrated computer systems with product and inventory control bar coding, medical/surgical distributors can increase product handling efficiency in areas of less than case quantities, bulk-order receiving, put away reporting, replenishment, picking, order checking, shipment staging, invoice preparation, inventory control, cycle counting, physician inventories, multi-product shipping containers, and return goods handling within the distribution process.

Medical/surgical healthcare facilities benefits

Healthcare providers experience a broad range of benefits using bar code technology. The quality of patient care is improved; there is increased accuracy in gathering data, staff productivity is enhanced; employee morale improves; and health issues (i.e., carpal tunnel syndrome) are eliminated by automating tedious manual repetitive tasks such as keyboarding. The purchasing and supply utilization and price information is tracked efficiently to reduce cost, and risk management is greatly enhanced through the ability to share more data between integrated systems.

Some specific departments benefiting from this technology include: Materials Management for purchasing and supply distribution; Laboratory for specimen processing; Medical Records for patient record tracking; Radiology for x-ray jacket tracking; Kidney Dialysis in reprocessing cells; Human Resources for time and attendance; Security for employee access to parking lots and employee entrances; Pharmacy for medication administration and risk management; Patient Accounting to identify total cost per procedure; and many other applications where data capture can be automated.

Safe Medical Devices tracking

In 1990, Congress enacted the Safe Medical Devices Act (SMDA) to strengthen the authority of the Food and Drug Administration (FDA) to regulate devices and expedite and facilitate the removal of dangerous defective devices from the market. This regulation requires manufacturers of specific devices to develop, document, and operate a tracking system that will allow them to quickly notify all distributors, health professionals, or patients of a recall due to the existence of a serious health risk. Each manufacturer must be able to trace each device throughout the distribution system all the way to the patient. Distributors, including home medical equipment suppliers and other rental companies, healthcare facilities, and licensed practitioners, all must participate in the tracking system. Bar coding offers an efficient and economical method of compliance.

U.S. Department of Defense

The Department of Defense (DOD) has taken a leadership position to bring full implementation of industry standard UPN bar coding. As part of its decision to use commercial medical products distributors and products in standard commercial packaging, the DOD mandated, with appropriate deadlines, that all manufacturers providing medical products for DOD facilities must have purchase unit of measure packages identified by a health industry standard bar code and human readable representation. Other industry trading partners have followed the DOD with similar requirements. These industry-standard bar code representations are collectively referred to as Universal Product Numbers (UPNs).

Universal Product Numbers (UPN)

Until now, the medical/surgical industry differed significantly from the pharmaceutical industry. In the latter, the National Drug Code (NDC) has been extremely successful in implementing a unique number, which identifies the specific drug and is recognized universally.

Now is the medical/surgical industry's turn to develop and implement such a numbering scheme. The Universal Product Number (UPN) is intended to unambiguously identify medical/surgical products in the supply chain, thereby simplifying product distribution. Each product at all levels of packaging are being assigned a unique UPN, consisting of either the HIBC or UCC primary data structure, by the product manufacturers.

HIDA has committed itself to developing grass-roots support for the UPN among major medical/surgical companies and their customers. The UPN has been endorsed by all member organizations represented on the HIBCC Board of Directors. In addition, the US Department of Defense (DoD) requires all manufacturers doing business with the DoD to identify and bar code their products with the UPN. Distributors doing business with the DoD must accept the UPN as the single ordering number for med/surg products.

Customers will be able to communicate their needs to their Group Purchasing Organizations (GPO) and trading partners without interpretation or cross-referencing. The UPN will increase both the speed and accuracy of the med/surg distribution system and decrease long term operating costs.

Everyone from the manufacturer to the consumer of med/surg items will benefit from the industry-wide adoption of the UPN.

- Providers/Customers will benefit the most. They will be able to identify and order needed items without extensive catalog research and shopping time. They will no longer have to maintain large databases and cross-references of the products they stock. They will be able to communicate their needs in a language that the entire industry can understand.
- Manufacturers will realize improved visibility of their products in the marketplace. They will be assured that a customer wanting to order their specific products will be able to identify and specify those products when ordering.
- Distributors will save because they will not have to develop and maintain multiple cross-references to track their product lines.
- Everyone benefits since the UPN facilitates the use of EDI, increasing the ease, speed and accuracy of ordering and distribution. The UPN will also allow the entire industry to capture demand/sales information and identify industry-wide trends.

The UPN identifies the “package level” of each product. This may require a change in the way trading partners maintain information in their systems. Each packaging iteration (case, box, each, etc.) will have a unique UPN.

Data processing issues associated with product identifiers concern how the information is stored and used in business applications. To be useful, product identifiers must be unique to allow systems to distinguish one product at a given level of packaging from another. Identifiers, properly considered, carry no other information other than what it is, not who makes it, what color it is, what it smells like, or how many there are of them. It doesn't matter whether identifiers are numeric or alphanumeric, fixed or variable length, strings or blobs, descriptive or encoded, or represented otherwise in a systems environment – only that they are unique.

In the healthcare industry, this requirement has resulted in the creation of the Universal Product Number (UPN), a unique identifier that combines manufacturer, item number and level of packaging information. The UPN can be encapsulated within either HIBC or UCC data structures. When discussing data processing, the focus should concern the processing UPNs, not symbologies or bar code data structures.

HIDA Position

In order to realize efficiencies in distribution to all levels of patient care, HIDA and the industry need medical/surgical manufacturers and labelers to identify all commercial packages with industry-standard product bar codes in the following levels of packaging:

- Shipping cases
- Intermediate packaging
- Larger unit-of-use packages
(Or the next smaller unit not yet bar coded)
- Very small unit-of use packages where practical (or the next smaller unit not yet bar coded)

The need for source-marked product bar codes has existed for years in the healthcare industry and that need continues to mount due to increasing pressure to control the costs of moving medical/surgical products. HIDA, therefore, puts forth the following with the objective of helping healthcare manufacturers better understand the requirements of the marketplace.

- Establish a policy of UPN bar coding the complete product line shipping cases, inner packs (intermediate packaging) and units of use (“eaches”). Add UPN bar codes as labels are changed, or as packaging supplies are replenished.

- Establish goals to complete the bar coding of all levels of packaging that are consistent with those set by the UPN Initiative. Goals for the completion of UPN bar codes on smaller packaging levels are suggested to be in no more than six month increments until all levels, including unit of use (each) where feasible, are completed.
- Print all UPN bar codes within their respective symbology specifications. This is very important. Bar code scanning equipment manufacturers ensure that their bar code readers are capable of successfully scanning all UPN bar codes that are printed within these respective specifications. It is critical for the manufacturer to verify both bar code accuracy and readability on all packing supplies. Bar code quality is best monitored via day-by-day use in the manufacturer's operations.
- Identify shipping cases, inner packages (intermediate packaging), and units of use (eaches) with a Primary Symbol.

In addition, where it is relevant, secondary bar coded information (quantity, expiration date, and lot number), should be provided on all packaging above the unit level in the bar code.

- Position the Primary Symbol on shipping cases according to the HIBC Supplier Labeling Standard for HIBC symbols, or according to the UCC/EAN specifications for UCC/EAN symbols. The most desirable bar code placement is on all four sides or, at a minimum, on two adjacent side panels.
- Print inner packs (intermediate packaging) with the symbol either directly or on labels on the end (narrower) panel of the package.
- On units of use (eaches), position the bar code format on the front panel or to the right of the front panel. The product number and U/M in human-readable form must accompany the bar code. If space limitations prevent bar coding on the front panel or to the right of the front panel, the bar code should be as near to the front panel as possible, with the natural bottom of the package being an unacceptable location.
- Manufacturers should use Industry Standard bar codes in their own internal operations wherever possible. Manufacturers/labelers will benefit immediately from productivity and quality enhancements. The use of highly reliable bar codes will ensure an ability to interface with trading partners' systems, enhance trade relations with providers, and improve care to the patient.

HIDA Bar Code Format Recommendation

HIDA supports the Bar Code formats that comprise the Universal Product Number (UPN) Initiative: HIBC-LIC and UCC/EAN.

The Universal Product Number (UPN) is intended to unambiguously identify medical/surgical products. Its motto, "One product - One number" is meant to signify the objective of the UPN Initiative: The use of standardized, manufacturer-assigned identifiers for all processes throughout the healthcare products supply chain. Each manufacturer must carefully evaluate its market requirements and current product identification system and determine which UPN format is most suitable for it. Any format which is compatible with the UPN Initiative's requirements is acceptable.

Where the manufacturer is in the process of making its bar code format decision, HIDA recommends considering the following attributes:

The HIBC format includes a flexible length (up to 13 characters), alpha numeric Product ID that can allow a manufacturer to include an existing catalog number in the UPN/bar code.

The UCC/EAN is used in the pharmaceutical industry and may be required in some retail channels.

Manufacturers with product catalog numbers greater than 13 positions

None of the existing industry standards will accommodate this size product/catalog number. If the manufacturer wishes to use the HIBC format UPN, then the product catalog number must be reduced to 13 characters or less. If the manufacturer wishes to use the UCC/EAN format UPN, then it must establish a numeric cross-reference using the UCC/EAN SCC-14 format until the new product/catalog numbering schemes can be implemented.

Secondary data structures

Manufacturer/labelers may use the secondary data structure to encode expiration date, quantity and lot/batch serial numbers. This data is very important for manufacturers' internal operations as well as distributors' operations. The secondary data structure is recommended for use on levels of packaging above the unit of use; however, it may be used on the unit of use where appropriate. Either format (HIBC-LIC or UCC) is acceptable regardless of the Primary Data Structure selected.

Identifying Shipping Containers

It is general practice for distributors to put multiple products into one shipping container. One example is when individual consumer units of various products are put into one corrugated shipping container. Another example is when multiple shipping containers of different products are shrink-wrapped on a pallet. These containers should be marked with labeling compatible with the "ANSI MH10 8M-1993" standard entitled, "Guidelines for Material Handling, Unit Loads and Transport Packages - Bar Code Symbols."

Those manufacturers using the HIBC UPN format can use the FACT Data identifiers, which are supported by the ANSI MH10 8M-1993 standard. Contact the HIBCC for detailed information regarding their use.

Those manufacturers using the UCC UPN format can use the SSCC-18 Shipping Container Code, which is supported by the ANSI MH10 8M-1993 standard. Contact the UCC for detailed information regarding its use.

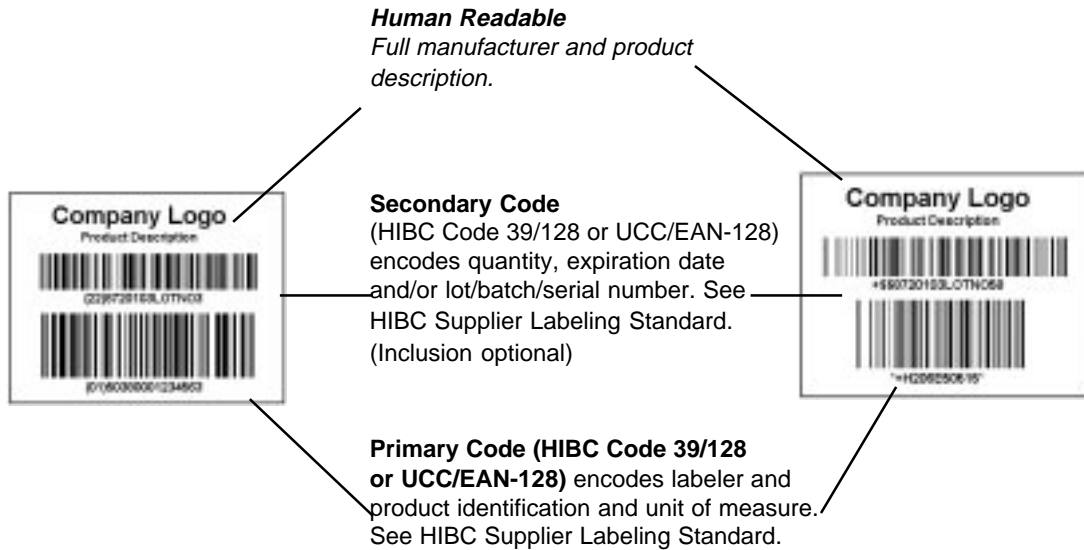
These symbols can be used to uniquely identify any transport container within the global supply chain. They are intended for use in conjunction with EDI to automate the receiving process.

The shipping company identifies the multi-product container to be shipped with a "license plate," and transmits detailed information about the contents of the shipment (and all the associated units, orders, and items contained within the shipment) via EDI to the receiving company utilizing the ANSI X12 856. The receiving company stores the transmitted information in their computer and customer service can then be alerted that their product is on its way. When the shipment arrives, the receiving company scans the license plate. The computer matches the license number to the EDI shipping data and displays the detailed contents of the container. The receiving clerk can then verify the contents and confirm accuracy or make the necessary changes.

Additional pallet labeling guidelines can be found in the "ANSI MH10 8M-1993" (Guidelines for Material Handling. Unit Loads and Transport Packages-Bar Code Symbols) document. Standards have been set for label size, address locations, and bar code formats. The ANSI MH10 8M-1993 Guidelines are available from ANSI, 11 West 42nd Street, 13th floor, New York, New York 10036. The telephone number for ANSI is (212) 642-4900. Email: info@ansi.org Web site: <http://www.ansi.org>

Examples

Bar Code Label



- Human readable manufacturer and product description should always be part of the bar code label.
- Human readable manufacturer and product description, and bar code information should be printed directly on the containers or printed on labels, or in any combination.
- Intermediate and shipper labels should be sized to fit the individual container (carton, shrink-wrap or corrugated).

Bar Coding Location Example for Shipping Case Packaging

Shipping Case Packaging Format

Placement on one long side and one short side preferred, as a minimum. Label may be one wraparound or two individual labels according to the labeler's preference. Use the UCC/EAN Applications Standard for Shipping Container Codes for symbol placement. All information also printed in human readable form.



Bar Coding Location Example for Shipping Case Packaging

Carton Format

Primary Symbol encodes manufacturer (labeler), product and unit of measure. Repeat human readable product identification.

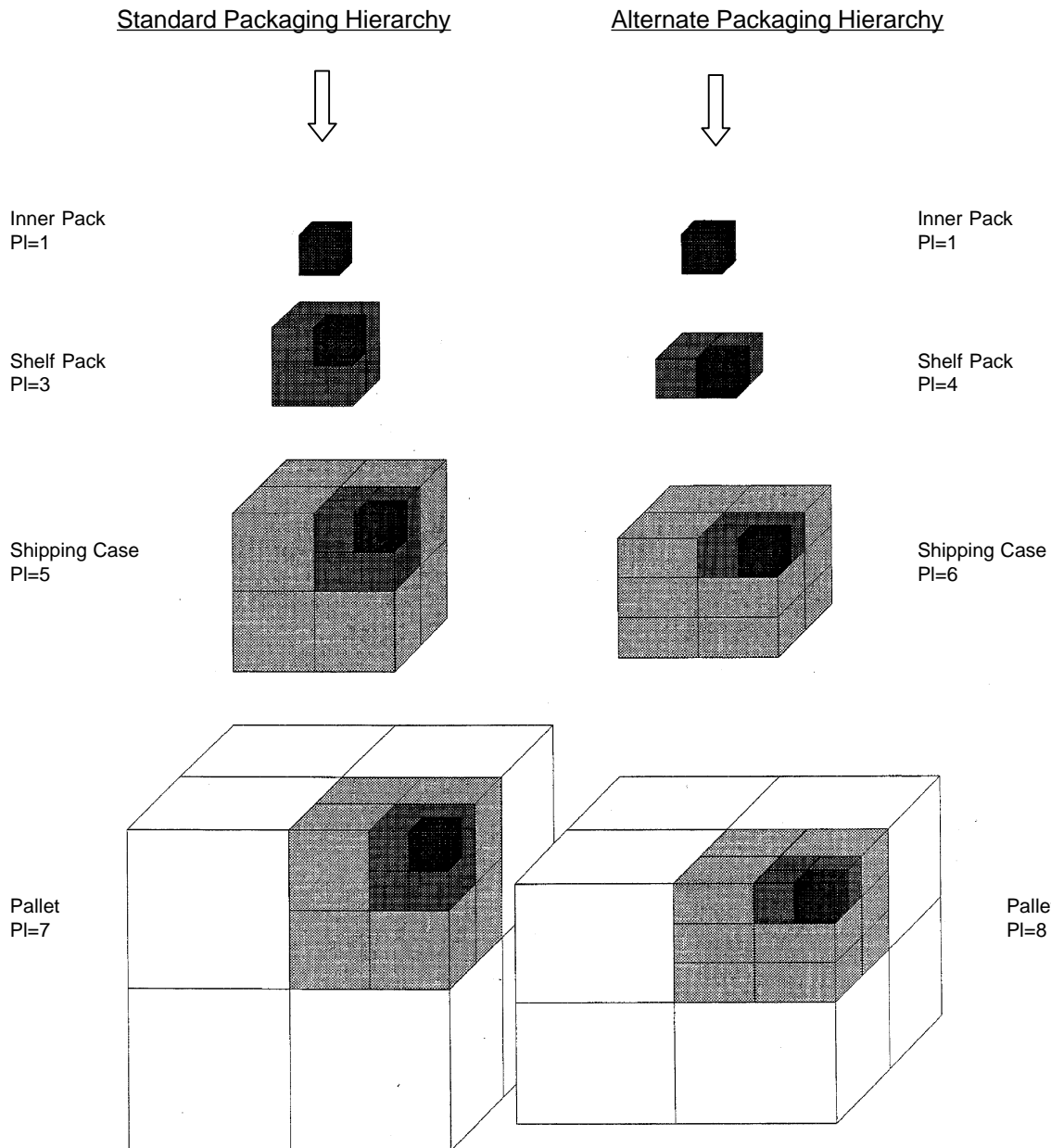


Unit of Use (Each) Format

Primary Symbol encodes manufacturer (labeler), product and unit of measure to the right of the front panel. Includes human readable product information.



Example Methods of Assigning Packaging Indicators for Standard and Alternate Packaging Hierarchies



Note: These are merely examples of packaging indicator assignments. Manufacturers can assign the numbers 1 through 8 to any level of packaging above the unit level. Two indicators are reserved: 0 for unit-of-use and 9 for variable quantity containers.

For Further Information

- ***ANSI MH10 8M-1993 Guidelines for Materials Handling***

ANSI
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- ***HIBC Supplier Labeling Standard***
HIBC Provider Applications Standard

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- ***UPC Symbol Specification Manual***
UCC/EAN-128 Application Identifier Standard
UCC/EAN Applications Standard for Shipping Container Codes

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